

## Laboratory Improvement Program Office - Certificate of Waiver Tests

Certificate of Waiver tests are tests which are approved by the FDA for home use and simple to perform. A certificate of waiver costs \$150 for two years. The following tests are waived:

CPT Code	Test/Manufacturer
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81002	Dipstick or tablet reagent urinalysis (non-automated)
81003QW	Bayer CLINITEK 50 Urine Chemistry Analyzer
82270	Fecal occult blood
84830	Ovulation tests - visual color comparison tests
81025	Urine pregnancy tests - visual color comparison tests
85651	Erythrocyte sedimentation rate - non-automated
83026	Hemoglobin - copper sulfate - non-automated
82962	Blood glucose by devices cleared by the FDA for home use.
82962	Hemocue "B" Glucose ( <b>only approved system for diagnosis</b> )
82950QW	Hemacue "B" Glucose System only; one hour post glucose
82951QW	Hemacue "B" Glucose System only; Glucose tolerance - 3 hour
82952QW	Hemacue "B" Glucose System only; Glucose tolerance - additional
85013	Spun microhematocrit
85013	Wampole STAT-CRIT Hct for Hematocrit
85018QW	Hemoglobin - single analyte instruments providing direct readout. (Hemacue)
82465QW	Johnson & Johnson ADVANCED CARE Cholesterol Test
82465QW	Boehringer Mannheim Corp. - Accu-chek InstantPlus Cholesterol test
82465QW	Chemtrak Accumeter Cholesterol
82465QW	Actimed Laboratories ENA.C.T. Total Cholesterol Test
82465QW	Cholestech LDX System, Total Cholesterol
83718QW	HDL
84478QW	Triglycerides
80061QW	Lipid Profile
82962QW	Glucose
83986QW	Nitrazine (pH) paper for body fluid pH
82273QW	Smith Kline Gastrocult Test
86588QW	Quidel Quickvue In-Line One-step Strep A (25 test kit)
86588QW	Binax Now Strep A Test
86588QW	Wyntek Diagnostics OSOM Strep A Test
86588QW	BioStar Aceavea Strep A Test (direct specimen only)
86588QW	Abbott Signify Strep A test (from throat swab only)
86588QW	SmithKline Diagnostics, Inc. ICON Fx Strep A Test (throat swab only)
86588QW	Applied Biotech Surestep Strep A
82044QW	Microalbumin - Boehringer Mannheim Chemstrip Micral

87072QW	Quidel QuickVue One-Step H. Pylori Test for Whole Blood
87072QW	Abbott FlexPack HP Test for Whole Blood
87072QW	Delta West CLOtest (Tri-Med Specialties) for Helicobacter Pylori
87072QW	GI Supply H-P Fast test system (Mycoscience Labs, Inc.)
87072QW	Serim Pyloritek test kit
87072QW	SmithKline Diagnosticcs FlexSure HP Test for IgG Antibodies to
87072QW	Helicobacter Pylori in Whole Blood
82985QW	LXN Fructosamine Test System
82985QW	LXN Duet Glucose Control Monitoring System (Fructosamine)
83036QW	Ames DCA 2000 Glycosylated Hemoglobin
83036QW	Bayer DCA 2000 Glycosylated Hemoglobin
85610QW	Boehringer Mannheim ITC ProTIME Microcoagulation System
85610QW	Boehringer Mannheim Coaguchek PST (patient self test) for Protime
86308QW	Wampole Mono-Plus (whole blood - infectious mononucleosis)
86308QW	Genzyme Contrast mono (whole blood - infectious mononucleosis)
86308QW	BioStar Aceava Mono Test (whole blood - infectious mononucleosis)
86308QW	LifeSign UniStep Mono Test (whole blood - infectious mononucleosis)
TBA*	STC Diagnostics QED A150 Saliva Alcohol Test
TBA*	STC Diagnostics QED A350 Saliva Alcohol Test
*to be announced	

There are no personnel requirements for waived tests. Anyone may perform waived tests. Anyone may direct a laboratory with a certificate of waiver.

Laboratories performing waived tests must provide quality health care for their patients. This means using good standards of practice. In a clinical laboratory this would mean:

1. Running controls each day that tests are performed
2. Keeping record of quality control (QC) results
3. Keeping records of patient test results
4. Participating in external quality control
5. Utilizing a quality assurance (QA) review system

Laboratories must notify the state agency within 30 days of changes in:

1. Ownership
2. Name
3. Location
4. Laboratory director